IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

CANOPY GROWTH CORPORATION, Plaintiff, v. GW PHARMA LIMITED and GW RESEARCH LIMITED, Defendant.	)	Civil Action No. 6:20-cv-01180-ADA **JURY TRIAL DEMANDED**

DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants GW Pharma Limited ("GWP") and GW Research Limited ("GWR") (collectively, "Defendants" or "GW"), by and through the undersigned attorneys, for their Answer, Affirmative Defenses, and Counterclaims to the First Amended Complaint of Plaintiff Canopy Growth Corporation ("Plaintiff" or "Canopy"), allege as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Defendants deny all allegations in Plaintiff's First Amended Complaint except those specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, and not as to any purported conclusions, characterizations, implications, or speculations that could arguably follow.

Defendants reply to the numbered allegations in Canopy's First Amended Complaint. To the extent that the headings or other nonnumbered statements in Canopy's First Amended Complaint contain any allegations, Defendants deny each and every allegation therein. Defendants deny that Canopy is entitled to the relief requested or to any other relief.

NATURE OF THE ACTION

1. Defendants admit that the Complaint purports to bring a civil action for patent infringement of United States Patent No. 10,870,632 ("the '632 patent"). Defendants deny that Plaintiff is entitled to any relief in this action.

THE PARTIES

2. On information and belief, admitted.

3. Defendants admit that GWP is a private limited company and is a wholly owned subsidiary of GW Pharmaceuticals Limited (formerly GW Pharmaceuticals PLC). Defendants admit GWP is incorporated under the laws of England and Wales, with its registered offices at Sovereign House Vision Park, Chivers Way, Histon, Cambridge, CB24 9BZ, United Kingdom. Otherwise, denied.

4. Defendants admit that GWR is a private limited company and is a wholly owned subsidiary of GW Pharmaceuticals Limited. Defendants admit GWR is incorporated under the laws of England and Wales, with its registered offices at Sovereign House Vision Park, Chivers Way, Histon, Cambridge, CB24 9BZ, United Kingdom. Otherwise, denied.

JURISDICTION AND VENUE

5. The allegations of paragraph 5 contain conclusions of law to which no response is required. To the extent a response is required, Defendants will not contest subject matter jurisdiction for purposes of this action only.

6. The allegations of paragraph 6 contain conclusions of law to which no response is required. Otherwise, denied.

7. The allegations of paragraph 7 contain conclusions of law to which no response is required. To the extent a response is required, Defendants will not contest personal jurisdiction for purposes of this action only.

8. Defendants admit that Defendants are wholly owned subsidiaries of GW Pharmaceuticals Limited (formerly GW Pharmaceuticals PLC). Defendants further admit that EPIDIOLEX® is an oral solution containing cannabidiol ("CBD") as its active ingredient. Defendants further admit that GWP manufactures the CBD used in EPIDIOLEX® and imports EPIDIOLEX® into the United States. Defendants admit that Paragraph 8 quotes or refers to cropped statements taken out of context from the cited exhibits. Otherwise, denied.

9. Defendants admit that paragraph 9 quotes or refers to cropped statements taken out of context from the cited exhibits. Otherwise, denied.

10. Defendants admit that EPIDIOLEX® has been prescribed to patients in Texas and in the Western District of Texas. Defendants admit that clinical trials for EPIDIOLEX® were conducted at sites across the United States, including in Austin, Texas. Otherwise, denied. Defendants deny that the CBD used in EPIDIOLEX® is produced using a process that infringes the '632 patent. The CBD used in EPIDIOLEX® is produced by a process that is substantially different from, and not covered by, the processes claimed in the '632 patent.

11. Defendants admit that GWP imports EPIDIOLEX®. Defendants further admit that non-party Greenwich Biosciences, Inc., a U.S. subsidiary of GW Pharmaceuticals Limited, takes title, markets, and sells EPIDIOLEX® in the United States. Defendants admit that EPIDIOLEX® is sold in Texas. Defendants deny that the CBD used in EPIDIOLEX® is produced using a process that infringes the '632 patent. The CBD used in EPIDIOLEX® is produced by a process that is substantially different from, and not covered by, the processes claimed in the '632 patent. The

allegations of paragraph 10 otherwise contains legal conclusions to which no response is required, or are otherwise denied.

12. Defendants admit that GWP manufactures the CBD used in EPIDIOLEX® and imports EPIDIOLEX® into the United States. Defendants further admit that non-party Greenwich Biosciences, Inc., a U.S. subsidiary of GW Pharmaceuticals Limited, takes title, markets, and sells EPIDIOLEX® in the United States. Defendants further admit that EPIDIOLEX® is marketed throughout the United States. Defendants admit that paragraph 12 quotes or refers to cropped statements taken out of context from the cited exhibits. Defendants deny that the CBD used in EPIDIOLEX® is produced using a process that infringes the '632 patent. The CBD used in EPIDIOLEX® is produced by a process that is substantially different from, and not covered by, the processes claimed in the '632 patent. Otherwise, denied.

13. The allegations of paragraph 13 contain legal conclusions to which no response is required. Otherwise, denied.

14. The allegation of paragraph 14 is a legal conclusion to which no response is required. To the extent a response is required, Defendants will not contest personal jurisdiction for purposes of this action only.

PATENT-IN-SUIT

15. Defendants admit that what appears to be a copy of the '632 patent is attached as Exhibit A. Defendants deny that the '632 patent was duly and legally issued. On information and belief, Defendants admit that Canopy is the owner by assignment of the '632 patent. Otherwise, denied.

BACKGROUND OF THE DISPUTE

16. Defendants admit that cannabidiol ("CBD") and Δ^9-tetrahydrocannabinol (THC) are compounds that can be extracted from cannabis plant material. Defendants further admit that EPIDIOLEX®, which contains the active ingredient CBD, is presently approved by the U.S. Food & Drug Administration ("FDA") for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, and tuberous sclerosis complex in patients 1 year of age and older. Defendants deny that the CBD used in EPIDIOLEX® is produced using a process that infringes the '632 patent. The CBD used in EPIDIOLEX® is produced by a process that is substantially different from, and not covered by, the processes claimed in the '632 patent. Otherwise, Defendants are without knowledge or information sufficient to form a belief as to the allegations of Paragraph 18, and on that basis deny them.

17. Defendants are without knowledge or information sufficient to form a belief as to the allegations of Paragraph 17, and on that basis deny them.

18. Defendants admit that the '632 patent purports on its face to claim priority to German Patent Application No. 100 51 427, filed on October 17, 2000, and that the named inventor is Adam Mueller. Defendants further admit that the '632 patent generally relates to methods for extracting CBD and/or THC using carbon dioxide ("CO_2"). Defendants further admit that the '632 patent purports to list potential therapeutic uses of CBD at col. 3, line 53 to col. 4, line 3. Otherwise, Defendants are without knowledge or information sufficient to form a belief as to the allegations of Paragraph 18, and on that basis deny them.

19. Defendants admit that they and / or other subsidiaries of GW Pharmaceuticals Limited are involved in the development, manufacture, and/or commercialization of cannabinoid therapeutics, including EPIDIOLEX®. Defendants further admit that EPIDIOLEX® is an oral

solution containing CBD as its active ingredient and that it is presently approved by the FDA for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, and tuberous sclerosis complex in patients 1 year of age and older. Defendants further admit that EPIDIOLEX® was first approved by the FDA on June 25, 2018 and that it became commercially available in the United States on November 1, 2018. Defendants admit that, due to EPIDIOLEX®'s effectiveness in treating its approved indications, EPIDIOLEX® has become a commercial success. Defendants admit the allegations of paragraph 19 purport to make statements about pricing and sales data for EPIDIOLEX® without context or citation to source materials. Defendants deny that the CBD used in EPIDIOLEX® is produced using a process that infringes the '632 patent. The CBD used in EPIDIOLEX® is produced by a process that is substantially different from, and not covered by, the processes claimed in the '632 patent. Otherwise, denied.

20. Defendants admit that in May 2006, GWP filed an opposition to EP 1 326 598, a European counterpart of the '632 patent, and that in October 2012, the European Patent Office revoked EP 1 326 598 at the conclusion of those proceedings. Defendants admit that U.S. Patent Application No. 10/399,362 was pending at the time the opposition to EP 1 326 598 was filed. Otherwise, denied.

21. Defendants admit that from 2015 to 2017, GWP considered an agreement with Bionorica and its partner Nateco, pursuant to which Nateco would extract CBD for use in pharmaceutical products. Defendants further admit that the parties could not reach suitable terms and a final agreement was never reached. Defendants admit that in 2017 GW PLC declined to take a license to the U.S. Patent No. 8,895,078. Otherwise, denied.

PATENT INFRINGEMENT CLAIMS

22. Defendants repeat and incorporate by reference their answers to each of the preceding Paragraphs, 1-21, as if fully set forth herein.

23. Defendants admit that the ’632 patent generally relates to processes for extracting THC and/or CBD from cannabis plant material. Defendants admit that Paragraph 23 quotes or refers to cropped statements taken out of context from the ’632 patent. Otherwise, Defendants are without knowledge or information sufficient to form a belief as to the allegations of Paragraph 23, and on that basis deny them.

24. Denied.

25. Denied.

26. The allegations of paragraph 26 contain conclusions of law to which no response is required. To the extent that a response is required, Defendants deny that the allegations of paragraph 26 form a complete and accurate characterization of the manufacturing process for EPIDIOLEX®, and therefore denies them. Defendants deny that the CBD used in EPIDIOLEX® is produced using a process that infringes the ’632 patent. The CBD used in EPIDIOLEX® is produced by a process that is substantially different from, and not covered by, the processes claimed in the ’632 patent.

27. The allegations of paragraph 27 contain conclusions of law to which no response is required. To the extent that a response is required, Defendants deny that the allegations of paragraph 27 form a complete and accurate characterization of the manufacturing process for EPIDIOLEX®, and therefore denies them. Defendants deny that the CBD used in EPIDIOLEX® is produced using a process that infringes the ’632 patent. The CBD used in EPIDIOLEX® is

produced by a process that is substantially different from, and not covered by, the processes claimed in the ’632 patent.

28. The allegations of paragraph 28 contain conclusions of law to which no response is required. To the extent that a response is required, Defendants deny that the allegations of paragraph 28 form a complete and accurate characterization of the manufacturing process for EPIDIOLEX®, and therefore denies them. Defendants deny that the CBD used in EPIDIOLEX® is produced using a process that infringes the ’632 patent. The CBD used in EPIDIOLEX® is produced by a process that is substantially different from, and not covered by, the processes claimed in the ’632 patent.

29. The allegations of paragraph 29 contain conclusions of law to which no response is required. To the extent that a response is required, Defendants deny that the allegations of paragraph 28 form a complete and accurate characterization of the manufacturing process for EPIDIOLEX®, and therefore denies them. Defendants deny that the CBD used in EPIDIOLEX® is produced using a process that infringes the ’632 patent. The CBD used in EPIDIOLEX® is produced by a process that is substantially different from, and not covered by, the processes claimed in the ’632 patent.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

34. Denied.

DEMAND FOR JURY TRIAL

Defendants admit the First Amended Complaint sets forth a demand for a trial by jury. Defendants also demand a trial by jury on all issues so triable.

PRAYER FOR RELIEF

Defendants deny that Plaintiff is entitled to the relief requested in its Prayer for Relief, or any other relief.

AFFIRMATIVE DEFENSES

Defendants assert the following defenses in response to the allegations of the First Amended Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. Defendants reserve the right to amend this Answer with additional defenses as further information is obtained. Defendants assert the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST DEFENSE
(Noninfringement)

Defendants have not infringed and do not infringe any valid and enforceable claim of the ’632 patent either literally or under the doctrine of equivalents.

Defendants have neither induced nor contributed to the infringement of any valid or enforceable claim of the ’632 patent.

SECOND DEFENSE
(Invalidity)

The asserted claims of the ’632 patent are invalid for failure to satisfy one or more provisions of the patent laws, including but not limited to, 35 U.S.C. §§ 101, 102, 103 and/or 112. For example, the asserted claims are invalid as obvious under § 103 because the asserted claims

would have been obvious at the time the alleged invention was made to a person having ordinary skill in the art, or fail to satisfy the requirements of § 112 because the Asserted Patents do not enable the alleged claimed inventions, fail to include an adequate written description, and/or are indefinite.

THIRD DEFENSE
Failure to State a Claim

Plaintiff's First Amended Complaint fails to state a claim upon which relief can be granted.

FOURTH DEFENSE
Limitation on Costs

Defendants incorporate by reference their second affirmative defense. One or more claims of the '632 patent are invalid under at least 35 U.S.C. §§ 101, 102, 103 and/or 112. Upon information and belief, Plaintiff has not disclaimed these invalid claims before the commencement of the present litigation. As such, Plaintiff may not recover costs under 35 U.S.C. § 288.

FIFTH DEFENSE
No Exceptional Case

Plaintiff cannot prove that this is an exceptional case justifying an award against Defendants under 35 U.S.C. § 285.

FIFTH DEFENSE
No Willful Infringement

Defendants have not willfully infringed any claim of the '632 patent.

RESERVATION OF DEFENSES

Defendants reserve the right to assert additional defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, defenses of unenforceability.

COUNTERCLAIMS

Counterclaim Plaintiffs GW Pharma Limited ("GWP") and GW Research Limited ("GWR") (collectively, "GW" or "Counterclaim Plaintiffs") for their counterclaims against Counterclaim Defendant Canopy Growth Corporation ("Canopy" or "Counterclaim Defendant"), allege as follows:

THE PARTIES

1. GWP is a private limited company incorporated under the laws of England and Wales, with its registered offices at Sovereign House Vision Park, Chivers Way, Histon, Cambridge, CB24 9BZ, United Kingdom.

2. GWR is a private limited company incorporated under the laws of England and Wales, with its registered offices at Sovereign House Vision Park, Chivers Way, Histon, Cambridge, CB24 9BZ, United Kingdom.

3. Upon information and belief, Canopy is a publicly traded corporation, incorporated in Canada, with its principal place of business at 1 Hershey Drive, Smiths Falls, Ontario, Canada, K7A 0A8.

NATURE OF THE ACTION

4. This is an action for declaratory judgments of non-infringement and invalidity of U.S. Patent No. 10,879,632 ("the '632 patent"). These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over the Counterclaims under at least 28 U.S.C. §§ 1331, 1338. Further, an actual, substantial and continuing justiciable controversy exists

between Counterclaim-Plaintiffs and Counterclaim-Defendant Canopy based on Canopy having filed a complaint for patent infringement against Counterclaim-Plaintiffs.

6. This Court has personal jurisdiction over Counterclaim-Defendant because, among other reasons, Canopy subjected itself to the jurisdiction of this Court by filing its First Amended Complaint here.

7. Venue is proper in this District as to these Counterclaims under 28 U.S.C. §§ 1391(b)-(c) and 1400(b) at least because the assertion of Canopy's infringement action against Counterclaim-Plaintiffs in this District gave rise to these Counterclaims. Canopy asserts in its First Amended Complaint that venue is proper in this District.

BACKGROUND OF THE DISPUTE

8. First approved by the U.S. Food & Drug Administration ("FDA") in June 2018 under New Drug Application N210365, EPIDIOLEX® (cannabidiol) oral solution ("EPIDIOLEX®") is presently approved in the United States to treat seizures associated with Lennox-Gastaut syndrome ("LGS"), Dravet syndrome ("DS"), or tuberous sclerosis complex ("TSC") in patients 1 year of age and older. The indications of EPIDIOLEX® are rare syndromes known to be resistant to conventional antiepileptic drugs. Accordingly, the approval of EPIDIOLEX® was a significant breakthrough for treatment of these diseases. EPIDIOLEX® is currently prescribed across the United States to improve the lives of patients suffering from these epilepsy syndromes.

9. The active ingredient in EPIDIOLEX® is cannabidiol ("CBD"). Cannabidiol is a compound found in the *Cannabis sativa* plant. GW Pharmaceuticals PLC and/or its subsidiaries established that CBD could be safely and effectively administered for treatment of DS, LGS, and

TSC through years of research and development work, culminating in multiple clinical trials. EPIDIOLEX® is the first and currently only FDA-approved CBD therapeutic.

10. The CBD used in EPIDIOLEX® is extracted using confidential and proprietary manufacturing processes. These were developed based on techniques for extraction with CO_2 solvent known well before the alleged priority date of the ’632 patent.

11. As described further below, the manufacturing process for the CBD used in EPIDIOLEX® does not infringe any valid claim of the ’632 patent.

12. Between 2015 and 2017, GWP considered a potential agreement with Bionorica and its partner Nateco, pursuant to which Nateco would prepare CBD extracts for incorporation into pharmaceutical products. Suitable terms could not be reached, and the parties ultimately did not pursue the collaboration. GWP proceeded to manufacture EPIDIOLEX® using CBD extracted according to its own processes.

13. While the parties were still discussing a potential agreement, representatives for Bionorica, including Bionorica’s outside counsel, approached GW Pharmaceuticals PLC (“GW-PLC”) regarding a license for U.S. Patent No. 8,895,078. GW-PLC was not interested in and did not agree to take a license to the ’078 patent.

14. The manufacturing process for EPIDIOLEX® does not infringe any valid claim of the ’078 patent, and Canopy has not asserted the ’078 patent in this case.

15. On October 15, 2012, EP 1 326 598, a European counterpart to the ’078 and ’632 patents, was revoked by the European Patent Office as a result of opposition proceedings brought by GWP.

THE ’632 PATENT

16. The ’632 patent, entitled “Process for Producing an Extract Containing Tetrahydrocannabinol and Cannabidiol from Cannabis Plant Material, and Cannabis Extracts,” was issued by the United States Patent and Trademark Office (“USPTO”) on December 22, 2020. Counterclaim-Plaintiffs incorporate by reference Exhibit A of Canopy’s Complaint, which is a copy of the ’632 patent.

17. The ’632 patent identifies Adam Mueller as the sole inventor and on its face identifies Bionorica Ethics GmbH as the assignee.

18. On information and belief, Canopy is the owner by assignment of the ’632 patent.

19. The specification of the ’632 patent states that the alleged invention “relates to a method for producing an extract from *cannabis* plant matter, containing tetrahydrocannabinol, cannabidiol and optionally the carboxylic acids thereof.” ’632 patent at Abstract.

20. The specification of the ’632 patent further states that, according to the alleged invention,

> [P]lant material is extracted with the aid of CO_2 under supercritical pressure and temperature conditions at a temperature in the range of approx, 31° C. to 80° C. and at a pressure in the range of approx. 75 bar to 500 bar, or in the subcricital [sic] range at a temperature of approx. 20° C. to 30° C. and a supercritical pressure of approx. 100 bar to 350 bar; or extracted under subcricital [sic] pressure and temperature conditions; and the obtained primary extract is separated under subcricital [sic] conditions, or under conditions that are subcricital [sic] in terms of pressure and supercritical in terms of temperature.

’632 patent at 5:10-20.

21. The ’632 patent has 25 claims, of which claims 1 and 14 are independent.

COUNT I
Declaratory Judgment of Non-Infringement

22. Counterclaim-Plaintiffs reallege and incorporate paragraphs 1-21 as though fully set forth herein.

23. Upon information and belief, Canopy possesses rights, title, and interest in the ’632 patent sufficient to have standing to assert claims for infringement of the ’632 patent.

24. Counterclaim-Plaintiffs have not infringed and do not infringe any valid and/or enforceable claim of the ’632 patent, directly or indirectly, literally or under the doctrine of equivalents, by making, using, selling, and/or offering for sale EPIDIOLEX®.

25. A substantial, immediate, and real controversy exists between Canopy and Counterclaim-Plaintiffs regarding whether Counterclaim-Plaintiffs infringe the ’632 patent by making, using, selling, and/or offering for sale EPIDIOLEX®. A judicial declaration is necessary to determine the parties’ respective rights regarding the ’632 patent.

26. Counterclaim-Plaintiffs seek a judgment that the manufacture, use, sale, offer for sale and/or importation into the United States of EPIDIOLEX® has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid and enforceable claim of the ’632 patent, either literally or under the doctrine of equivalents.

27. By way of example, and as explained below, the process for manufacturing EPIDIOLEX® does not meet the limitations of claims 1 and 14 of the ’632 patent.

28. Independent claim 1 of the ’632 patent recites:

> A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD), and optionally the carboxylic acids thereof, from a *cannabis* plant material or a primary extract thereof, said process comprising:
> (1) subjecting the *cannabis* plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components; and
> (2) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol, and optionally the carboxylic acids thereof, from the CO_2.

29. Independent claim 14 of the ’632 patent recites:

> A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD) from a *cannabis* plant material or a primary extract thereof, said process comprising:
> (1) decarboxylating cannabinoid carboxylic acids in the cannabis plant material or primary extract thereof;
> (2) subjecting the decarboxylated cannabis plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components; and
> (3) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol from the CO_2.

30. The manufacturing process for EPIDIOLEX® does not infringe any claim of the '632 patent. By way of example, both claims 1 and 14 of the '632 patent require "subjecting the . . . *cannabis* plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components . . .".

31. As indicated in confidential manufacturing documents produced in this litigation, *e.g.* GW PHARMA_0000764-0000778, the commercial manufacturing process for EPIDIOLEX® does not involve a step of "subjecting the . . . *cannabis* plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components . . .". The manufacturing process for the CBD used in EPIDIOLEX® does not infringe the claims of the '632 patent for at least this reason.

COUNT II
Declaratory Judgment of Invalidity

32. Counterclaim-Plaintiffs reallege and incorporate paragraphs 1-31 as though fully set forth herein.

33. Canopy's First Amended Complaint accuses Counterclaim-Plaintiffs of infringing claims of the '632 patent by making, using, selling, offering for sale in the United States, and/or importing into the United States EPIDIOLEX®. Thus, a substantial, immediate, and real

controversy exists between Canopy and Counterclaim-Plaintiffs regarding whether the claims of the ’632 patent are valid.

34. The claims of the ’632 patent are invalid because they fail to comply with one or more sections of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103 and/or 112, including as set forth in Counterclaim-Plaintiffs’ Preliminary Invalidity Contentions served on Canopy on June 29, 2021. Counterclaim-Plaintiffs incorporate by reference their Preliminary Invalidity Contentions as though fully set forth herein.

35. Processes using “CO_2 in liquefied form under subcritical pressure and temperature conditions” to extract components from plant material were known before the alleged priority date of the ’632 patent.

36. For example, before the alleged priority date of the ’632 patent, processes using liquid at a pressure below the critical pressure for CO_2, and at a temperature below the critical temperature for CO_2, had been used for the commercial extraction of hops components to flavor beer.

37. A person of ordinary skill in the art would have understood, based on the successful use of liquid CO_2 at subcritical pressure and temperature to extract other plant components (including hops), that such methods could be applied to extract CBD from cannabis with a reasonable expectation of success.

38. For this and other reasons, Counterclaim-Plaintiffs are therefore entitled to a declaration that the claims of the ’632 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiffs respectfully request that the Court enter judgment in favor of Counterclaim-Plaintiffs and pray that the Court grant the following relief:

(a) A judgment that Counterclaim-Plaintiffs do not infringe, either directly or indirectly, any claim of the '632 patent, either literally or under the doctrine of equivalents, based on the manufacture, use, sale, offer for sale and/or importation into the United States of EPIDIOLEX®, and that they are therefore not liable for damages or injunctive relief as a result of these activities;

(b) A judgment that the claims of the '632 patent are invalid;

(c) A judgment that this is an exceptional case in favor of Counterclaim-Plaintiffs and awarding their attorneys' fees pursuant to under 35 U.S.C. § 285;

(d) A judgement awarding Counterclaim-Plaintiffs their costs and expenses; and

(e) Any and all such other relief as the Court determines to be just and proper.

Dated: July 28, 2021

Respectfully submitted,

/s/ Steven M. Zager

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that counsel of record who are deemed to have consented to electronic service are being served today, July 28, 2021, with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(b)(1).

/s/ Steven M. Zager
Steven M. Zager